UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Judge Honorable Joel Schneider, Magistrate Judge

PLAINTIFFS' FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS TO ALL API AND FINISHED-DOSE MANUFACTURING DEFENDANTS

TO ALL DEFENDANTS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 34 and Local Civil Rule 34.1, Plaintiffs propound the following discovery requests upon each defendant:

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DEFINITIONS:

"Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

"API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).

"Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

"Communication(s)" means the transmittal of information, in the form of facts, ideas, inquiries, documents or otherwise, and includes all transmissions of information received or transmitted by you, including correspondence, regardless of whether you are an author or addressee of such transmittal.

"Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is January 1, 2010 to the present.

"Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.

"TPP" refers to Third Party Payors, including health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plants, third party payers, and any other health benefit provider in the United States of America and its territories.

"Valsartan" means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug.

"You," "your" or **"defendant"** shall be used interchangeably and refers to the parties to which these requests are directed.

DOCUMENTS TO BE PRODUCED

I. CORPORATE ORGANIZATION

1. Produce organizational charts setting forth the corporate organization for each named defendant, from January 2010 to the present as follows:
    a. General corporate organizational charts for each defendant, including any affiliated entities involved in the manufacture, testing, distribution, or sale of valsartan;
    b. Medical affairs/clinical affairs department, or the equivalent;
    c. Quality assurance department, or the equivalent;
    d. Manufacturing department, including any departments involved in the manufacturing process for valsartan;
    e. Procurement Department;
    f. Sales department;
    g. Marketing department;
    h. Research and development department;
    i. Department(s) responsible for designing, funding, or supervising clinical trials (including all Phase I, II, III, and IV);
    j. Regulatory department;
    k. Department responsible for epidemiology and/or statistical analysis;
    l. Professional education department;
    m. Department(s) responsible for establishing or maintaining relationships involving valsartan, with any other defendant named in this MDL.
2. From 2010 to the present, produce documents sufficient to demonstrate:
    a. All corporate officers;
    b. All members of the Board of Directors;
    c. All persons or entities which own or owned 5% or more of defendant's common stock; and
3. To the extent you conduct business relating to valsartan with any other defendant in the above-captioned MDL, produce documents sufficient to demonstrate the nature, extent, and length of this business relationship.

II. RELEVANT CUSTODIANS

4. Produce documents sufficient to identify the corporate employees or third parties responsible for or involved in the (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, and (16) communications with private individuals or entities, with regard to valsartan, and/or the ingredients thereof.

III. POLICIES AND PROCEDURES

5. Produce all documents setting forth all draft and final versions of policies, procedures, standard operating procedures, or protocols for or relevant to the (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, and

(16) communications with private individuals or entities, with regard to valsartan, and/or the ingredients thereof. In addition, provide all indexes or lists of the requested documents.

IV. AGREEMENTS

For the following requests, the relevant time period should begin on the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.

6. Produce all formal and informal agreements, contracts, or licenses that the answering defendant is a party to, with regard to (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, (16) communications with private individuals or entities, and (17) procurement, with regard to valsartan and/or its ingredients.
7. Produce all documentation, including agreements, draft agreements, memoranda, and physician expense reports, relating, referring to or embodying any attempt by defendant to retain, engage or otherwise provide financial support or item of value to any person with regard to proposed or actual scientific or medical study of valsartan, from January 1, 2010 to the present.
8. Produce all documents relating, referring to or embodying any discussions, negotiations or contracts to engage any third party to represent your interests before the FDA or any regulatory authority, or any Committee or subcommittee thereof, in regard to valsartan, including, but not limited to, retainer agreements or consultant agreements.
9. Produce all documents relating, referring to or embodying the retention of persons in any medical or scientific discipline to study, assess or analyze the safety of valsartan by or on behalf of any defendant, whether retained directly by any defendant or otherwise.

V. INTRA-DEFENDANT COMMUNICATIONS

10. All communications between any of the defendants related to (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, and (16) communications with private individuals or entities, with regard to valsartan and/or the ingredients thereof.

VI. ANDA AND DMF

11. To the extent any ANDA file for any valsartan was not produced in whole or in part during Core Discovery, produce the entire file, whether or not ultimately approved, beginning from the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.

12. Produce all correspondence with the FDA concerning any ANDA for valsartan, whether or not ultimately approved, beginning from the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.
13. Produce all documents containing the list of ingredients in valsartan, which were provided to any regulatory authority, beginning from the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.
14. Produce all documents relating to New Drug Applications filed by you relating to valsartan, beginning from the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.
15. Produce all complete drug master files for valsartan.

VII. LITIGATION AND DOCUMENT PRESERVATION

16. Produce all document retention or destruction policies in effect from January 1, 2010 to the present.
17. Produce documents sufficient to show the name, case caption, attorney, and/or status of any lawsuit filed against you relating to valsartan contamination.
18. Produce all documents upon which Defendant relies to support each and every affirmative defense asserted in the Answer or which you may assert.

VIII. MANUFACTURING

For the following requests, the relevant time period should begin on the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.

19. Produce all documents with regard to the manufacturing process for the active pharmaceutical ingredient in valsartan, including any modifications thereto.
20. Produce all documents with regard to the machines, materials, and substances (including but not limited to new or recycled solvents, tainted or contaminated solvents) utilized in the manufacturing process for the active pharmaceutical ingredient in valsartan, including specifications, manuals, material safety data sheets, machine settings and calibrations, and any modifications thereto.
21. Produce all documents (including photographs or video) with regard to any testing or inspections of the machines, materials, and substances utilized in the manufacturing process for the active pharmaceutical ingredient in valsartan.
22. Produce all documents setting forth the manufacturing/fabrication/production process for the finished drug formulation of valsartan sold by you or any of your affiliated entities,, including any quality assurance and testing, and any modifications thereto.
23. Produce all documents identifying any patented device, machine, or technology utilized in the manufacture or testing of valsartan.
24. Produce all documents relating to all patents filed by you or employees and/or agents associated with you to any foreign regulatory body regarding any manufacturing processes

associated with the creation or manufacturing of valsartan, including all supporting documentation and/or correspondence associated with the filing of those patents.

25. Produce documents which evidence the name, address, and role of any third party which supplied you with valsartan or any ingredient, material, or component used in the manufacture of valsartan, and any evaluation or testing thereof.
26. Produce all certificates of analysis or similar documents concerning valsartan, or documents and communications concerning the same.
27. Produce complete documentation setting forth (1) each lot, batch, or other production quantity of valsartan manufactured, purchased, or sold by defendant (including discarded or recalled lots or batches), (2) the dates of manufacture/production for each, (3) the solvent(s) (including residual or reused solvents) utilized in the manufacture of each, and (4) any information you had or have with regard to potential risks of the use of any solvent utilized including residual or reused solvents.
28. Produce all documents relating to all scientific journal articles submitted to any academic or scientific publication written or drafted in whole, or in part, by your employees or scientists who received funding or other forms of compensation from you, regarding the manufacturing of valsartan, including any final version, any drafts, edits, peer reviewed feedback, as well as all communications regarding any possible submission, acceptance or rejection of those journal articles.
29. All documents and communications between you and any third party, outside consultant, university, or individual scientist regarding the manufacturing process associated with the creation of valsartan, including but not limited to the tetrazole ring formation process. These documents should include requests to study the manufacturing process used to create valsartan, exchange of data regarding the manufacturing process used to create valsartan, requests to draft academic journal articles regarding the manufacturing process used to create valsartan, and all documents sufficient to show the payments made and/or contracts between you and those third parties.

IX. BIOEQUIVALENCE

For the following requests, the relevant time period should begin on the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.

30. All documents regarding the bioequivalence of any valsartan sold or manufactured (in whole or in part) by you to the Reference Listed Drug ("RLD"), including but not limited to, testing, correspondence with the FDA, and certifications of bioequivalence.
31. All documents and communications regarding the equivalence of any valsartan sold or manufactured (in whole or in part) by you to their RLD, including all marketing materials regarding the equivalence of your products with the RLD.
32. All documents and communications regarding the identification by any person or entity of any valsartan manufactured, utilized, or sold by or to you as not being bioequivalent to the RLD.
33. All documents and communications relevant to valsartan entries in the FDA's "Orange Book."
34. All documents and communications regarding any patent litigation between you and either the Brand Manufacturer of the RLD regarding valsartan, or other generic companies which had

filed an ANDA application for a valsartan product including all filings, briefings, exhibits, citizen petitions, and/or correspondence with the FDA or another regulatory agency.

X. TESTING

For the following requests, the relevant time period should begin on the date you first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest.

35. Produce all documents setting forth the planning, occurrence, or results of any testing (including chromatography) of valsartan that had the potential to directly or indirectly identify impurities or contamination.
36. Produce all documentation with regard to the first test that indicated contamination of valsartan that was potentially due to a nitrosamine, whether or not identified at the time.
37. Produce all documentation with regard to each notification to defendant of contamination of valsartan that was, or potentially was, due to a nitrosamine, including the full documentation of the testing and analysis that led to the identification of the actual or potential contamination. In connection with this request, separately identify the first such notification.
38. Produce all documents or communications with regard to the actual or attempted detection of impurities or contaminants in valsartan or any component or ingredient thereof, including chromatographs, and intermediate testing.
39. Produce all documents with regard to evaluation by an employee of defendant or a third party, of the health risks of valsartan contamination.
40. Produce all documents relating, referring to or embodying studies on the safety, ingredients, impurities, and contamination, of valsartan conducted by any third parties, including, but not limited to, those conducted by Contract Research Organizations (CRO), educational institutions, publicly or independently funded groups, competitors, trade groups or associations, regulatory entities, irrespective of whether such studies were conducted at the direction of Defendant.
41. Produce all documents concerning any receipt, discussion, studies, analysis or review of clinical experience reports for valsartan, including, but not limited to, formally submitted adverse reaction reports, communications (whether written or oral), case reports, published clinical experience reports, or any other such report made known to Defendant concerning valsartan including, but not limited to: 1) the relationship between the use of contaminated valsartan and potential or confirmed injuries; b) investigator reported events identified by patient number and relevant records; and c) any employee or consultant who reviewed and/or adjudicated such events for causation.
42. As to any clinical or animal study regarding valsartan, whether or not sponsored by, financed by, undertaken by, or suggested by Defendant, provide all documents concerning said study, including, but not limited to, analysis and conclusions, engagement letters, contracts, agreements with investigators, agreements with study locations, protocols, status reports, raw data, summary of findings, internal memoranda, drafts of reports, final reports, manuscripts, submissions to publishers, submissions to any regulatory authority.
43. Produce all documents relating, referring to or embodying any epidemiology studies or analyses known to defendant regarding valsartan, including but not limited to, any provided to or received from any regulatory authority, SAS data sets, combined analysis or pooled analysis whether or not published in medical literature or submitted to any regulatory authority,

study hypotheses, test protocols, data compilations, summaries of results, drafts of reports, final reports, published or unpublished articles or studies, presentations and poster sessions, compensation, engagement of investigators, investigators' brochures, and internal memoranda.

44. Produce documents sufficient to show (a) all testing, prior to any recall, of valsartan you manufactured or sourced, (b) all testing, after any recall, of valsartan you manufactured or sourced, (c) the results of the foregoing testing; (d) any testing that was considered but not performed before or after any recall, including the reason(s) why such testing was not performed, and (e) to the extent any lot, batch, or other production quantity was not tested for impurities or contamination, complete documentation with regard to the reason(s) why no such testing was performed.

XI. NITROSAMINES AND CONTAMINATION

45. Produce complete documentation identifying each lot, batch, or other production quantity of valsartan, and whether and how or why: (a) each was confirmed to be contaminated and the quantification of the contamination; (b) each was assumed to have been contaminated and the quantification of the contamination; (c) each was confirmed not to be contaminated; (d) each was assumed not to be contaminated, and (e) each was not confirmed or assumed to be contaminated.
46. Produce all documents with regard to any nitrosamine compound, including but not limited to NDMA, NDEA, NMBA, and any other nitrosamine or carcinogenic contaminant that has been directly or indirectly tested for and/or identified in valsartan or any other API or finished drug manufactured, formulated, distributed, or sold by the answering defendant.
47. Produce all documents evidencing any testing or research conducted by you to determine the existence or amount of contamination in any valsartan API or finished drug formulation. .
48. Produce all documents and communications with regard to the health risks due to contamination of valsartan with any nitrosamine or other carcinogenic substance.
49. Produce all studies, data, or other scientific or medical information reviewed or considered by any employee with regard to the health risks due to contamination of valsartan with any nitrosamine or other carcinogenic substance.
50. Produce all formal or informal reports or complaints by or to any person or entity with regard to valsartan contamination.
51. Produce every document relating, referring to or embodying any opinion by a physician, or a scientist, or a medical or scientific expert, given after the first notification of potential nitrosamine contamination of valsartan, regarding the safety or efficacy of valsartan including, but not limited to internal documents, reports prepared in legal proceedings, opinions expressed in depositions or trial, reports submitted to scientific journals, opinions expressed at medical conferences and opinions provided as testimony, reports or statements to the FDA or any regulatory authority, or any advisory committee thereof.

XII. REGULATORY CORRESPONDENCE AND DOCUMENTS

52. Produce all regulatory documentation and communications with regard to contamination or recalls of valsartan.

53. Produce all regulatory documentation and communications with regard to any aspect of the manufacturing process for valsartan.
54. Produce transcripts, notes, memoranda, or other documentation of any hearings or other proceedings or meetings which took place at or with any regulatory agency relating to the actual and/or potential contamination or recall of valsartan.
55. Produce all documents with regard to any FDA Advisory Panel meetings regarding valsartan contamination, including but not limited to:
    a. All documents relating or referring to any communications between Defendant (or any agent or consultant of Defendant), and the FDA or any Advisory Panel Member;
    b. All documents relating to or referring to any financial contributions or other items of value provided by Defendant to Panel Members or their institutions/organizations; and
    c. All documents relating, referring to or embodying minutes of meetings, agendas, dossiers, submissions, test summaries, internal memoranda regarding strategies and issues, Questions and Answers, scheduling, or any other documents concerning the Advisory Panel, submissions thereto, or the topic(s) discussed.
56. Produce all Establishment Inspection Reports and related documentation (including photographs or video) concerning your facilities or the facilities of any other defendant relating to valsartan or any equipment or systems used in the manufacture, fabrication, packaging, distribution, or sale of valsartan.
57. Produce all documents relating, referring to or embodying all inspection reports (including 483s, detention reports, and warning letters) or consent decrees which pertain in any way to valsartan contamination or any facility in which contaminated valsartan was manufactured, marketed, distributed or otherwise stored.
58. Produce complete documentation regarding any CAPAs (Corrective and Preventative Actions) relating to valsartan, including documentation showing what caused the CAPA to be opened and/or closed.
59. Produce all documentation, and related communications, of any complaints or third party communications to or from any regulatory agency with regard to actual or potential valsartan contamination.
60. Produce all documentation, including source files, for any MAUDE or other adverse event reports submitted to any regulatory agency with regard to valsartan contamination, and any related communications.
61. Produce complete files for all formal or informal adverse event reports and/or MedWatch reports concerning valsartan, including: a) causation analyses, b) summaries (including, but not limited to, computerized data), analysis or interpretations of any such adverse event report(s) (including any post-marketing submissions); and c) documents which discuss or refer to any adverse event report, or any summary, analysis or interpretation thereof.
62. Produce all databases maintained by you concerning both domestic and international formal and informal adverse event reports and/or MedWatch reports, including the underlying medical information and raw data maintained by you.
63. Produce all filings with the Securities and Exchange Commission (SEC), addressing any issues related to the sale of contaminated valsartan, including Forms 10-K, 10-Q, 8-K, and proxy statement (Schedule 14A), whether such filings are tentative, final, definitive, or supplemental.
64. Produce complete documentation of any communications with any state regulatory or health authorities regarding valsartan ingredients, purity, contamination, or pricing.

65. Produce all documents and communications concerning, with respect to valsartan, all efforts to comply with Current Good Manufacturing Practices (cGMPs), and any actions or inactions that did not meet or might not have met cGMPs.

XIII. COMPLAINTS AND RECALLS

66. Produce all documents and communications with regard to any consideration or implementation of a recall due to contamination of valsartan.
67. Produce all draft recall notices with regard to contamination of valsartan.
68. Produce all final recall notices with regard to contamination of valsartan.
69. Produce all documents and communications relating to or directly with any customer or consumer relating to the recall (or non-recall) of valsartan due to contamination.
70. Produce all documents and communications relating to communications directly with physicians relating to the recall (or non-recall) of valsartan due to contamination.
71. Produce all documents and communications with any person or entity from or to which you purchased or sold valsartan, with regard to valsartan contamination.
72. Produce all documents and communications with regard to the scope of any recall considered or implemented with regard to valsartan contamination.
73. Produce all documents and communications with regard to any complaint or concern raised by any person or entity relating to the quality or purity of valsartan.
74. Produce all documents or communications concerning any actual or potential import or export alerts relating to valsartan contamination.
75. Produce all documents and communications concerning any refunds that you paid to purchasers of valsartan in the United States from January 1, 2010 to the present, including but not limited to retail pharmacies, direct purchasers, wholesale distributors, and TPPs.
76. Produce all documents and communications regarding recall of valsartan, provided to consumers, physicians, and TPPs, including lists sufficient to show all persons or entities who received communications notifying them of the recall, the contents of all communications contained in the letters notifying persons of the recall, documentation tracking all correspondence and communications related to the recall, all drafts of letters or other communications created to notify consumers of the recall.
77. Produce all documents relating, referring to or embodying the hiring or retention by any Defendant or by any other person or entity acting on any defendant's behalf, of any public relations firm or any law firm specializing in drug regulatory practices to participate in, orchestrate, organize or otherwise direct any evaluation of recall discussions for valsartan and produce all documents regarding said engagement, including, but not limited to, questions and answers, talk papers, scripts for telephone calls, creation of special advisory or consulting boards, gestures to demonstrate concern for victims, donations to causes important to victims, retention of scientific or medical researchers, advisors or experts and other such public relations strategies.
78. **Note: this request is only directed to API manufacturer defendants and FDA liaison defendants.** Produce all documents with regard to, or communications with, Novartis concerning valsartan, including but not limited to, documents or communications relating to testing or evaluation of valsartan, contamination, impurities, recalls, pre-commercial negotiations, contracts (including all draft contracts), product specifications, testing specifications, complaints, responses to complaints, investigations, meeting notes, presentations, and communications with any regulatory authority.

XIV. WARRANTIES AND STATEMENTS

79. Produce all versions of defendant's labeling for valsartan, together with a chart of the approval dates and in use dates for all versions that were utilized in the sale and marketing of valsartan.
80. Documents sufficient to show all (past and present) labels and packaging materials, including all associated documentation and disclosures provided to medical professionals, purchasers, including TPPs, consumers, wholesale distributors, retail pharmacies, and other direct and indirect purchasers of valsartan, for each NDC, Batch Number, and Lot Number of valsartan sold in the United States from January 1, 2010 to the present, including copies and drafts of all such materials, and documents sufficient to show the time period during which each exemplar was in use.
81. All advertisements, and sales and marketing material for valsartan utilized from January 1, 2010 to the present, and charts setting forth the approval date, in use dates, and medium (i.e. website, sales document, marketing brochure).
82. Produce final and draft versions of all documents provided to consumers upon purchase of valsartan, (i.e. package inserts, patient brochures).
83. Produce all communications between you and any medical association concerning any adverse health effects that may or may not or be associated with valsartan.
84. Produce documentation of any discussion or submission between Defendant and any medical association concerning any adverse events reported to be associated, regardless of causality, with valsartan..
85. Produce all communications with financial analysts or investors concerning the role of valsartan in your financial or business prospects, including but not limited to any transcripts, presentations or documents concerning any analyst conference call, or business briefing.
86. Produce all documents and communications evidencing questions from and responses to healthcare providers regarding the safety, quality, recall status, or purity of valsartan from June 1, 2018 to the present.
87. Produce all documents reflecting public statements made by you regarding valsartan quality, purity, contamination, safety, or manufacturing process,, including but not limited to drafts and final versions of annual reports, press releases, and investor presentations.
88. Produce all documents reflecting any communication between you and any consumers, medical professionals, healthcare insurers, PBMs, wholesale distributors, retail pharmacies, investors, analysts, or the media regarding valsartan.
89. Produce all documents with regard to any policy, procedure, or marketing strategy you used to market, advertise, promote, and/or sell valsartan from January 1, 2010 to the present.
90. Produce all documents and communications with the Centers for Disease Control (CDC), National Institutes of Health, World Health Organization, U.S. Drug Enforcement Agency, U.S. Department of Justice, or U.S. Attorney General relating to valsartan contamination.
91. Produce all documents relating to the investigative subpoenas and subsequent investigation from the United States Department of Justice, United States Senate, and/or any other federal or state entity, relating to valsartan contamination, including, but not limited to, the information requested and produced by defendant, as well as communications between the defendant and the federal or state entity which served the subpoenas and/or conducted the investigation.

92. Produce all documents relating, referring to or embodying any discussion or submission between defendant and any state government regulatory agency or any state medical society concerning valsartan, including agreements related to reimbursement for valsartan.

XV. SALE AND DISTRIBUTION

93. Produce complete documentation setting forth and/or demonstrating the complete supply and distribution chain for valsartan purchased, sold, or distributed by you, from the manufacture of the API through the final sale to the consumer.
94. Produce all documents relating to the sale and distribution of valsartan that reflect NDC, batch number, and lot number.
95. Produce documents sufficient to show all sales of valsartan to wholesalers, distributers, retailers, and consumers, including the total net sales, total number of pills and/or units sold, unit price, unit cost, profit margin, and market share by state or territory.
96. Produce all documentation relating to the due diligence performed (or meant to be performed) in selecting an API or finished dose manufacturer from which you purchased valsartan, including but not limited to policies and procedures.
97. Produce all documents and communications from any API manufacturer or finished dose manufacturer with regard to the manufacturing process, ingredients, quality, purity, or contamination relating to valsartan.
98. Produce all documents relating to your decision to purchase valsartan from any API or finished dose manufacturer, including documents you reviewed or relied on to make those decisions.

XVI. IDENTIFICATION OF PURCHASERS

99. Produce documents sufficient to identify all persons and entities (including consumers and TPP entities) who purchased, reimbursed, or paid or otherwise compensated you for valsartan you manufactured, sold or distributed in the United States. If available, produce documents sufficient to show these individuals' or entities' names, last known mailing addresses and email addresses, last known telephone numbers, date(s) of purchase, NDC Code(s), Batch Number(s), and Lot Numbers.
100. Produce all documents and communications between or among you and any named plaintiff, including consumers and/or TPP entities, including but not limited to MSP Recovery Services (including its assignors, Summacare, Emblem, and Connecticare) and Maine Automobile Dealers Association.

XVII. SALES AND PRICING

101. Produce all documents relating to valsartan sales you made in the United States to any purchaser (including, but not limited to, wholesalers, distributors, retailers and retail consumers), including documents that reflect total gross sales, total net sales, total number of units sold, unit price (gross and net), unit cost, cost of goods sold, profit margin, NDC, batch number, and lot number, on an annual basis, by, defendant, state, territory or the District of Colombia.

102. Produce all documents and communications relating to your market share for valsartan, or competition for market share for valsartan, in the United States.

103. All documents and communications relating to negotiations over price and terms of sale or distribution between any defendant and any purchaser or re-seller of valsartan.

104. Produce all documents and communications relating to any agreements or arrangements between you and any TPP entity (or any person acting on behalf of a TPP entity) that did, could, or may affect the quantity or price of valsartan purchased (including e.g., rebate agreements, etc.).

105. Produce all documents relating to any arrangements between you and any other person or entity that did, could, or may affect the quantity or price of valsartan purchased, including but not limited to rebate agreements.

106. Documents sufficient to identify all retailers and/or sellers (including but not limited to, retail pharmacies, mail order pharmacies) who have offered valsartan for sale in the United States and territories from January 1, 2010 to the present, including but not limited to the name, location, and sales volume for each such retailer, as well as the relevant NDC, Batch Numbers, and Lot Numbers for each seller or retailer, where available.

107. For each month from January 1, 2010 to the present, produce all documents relating to your actual and projected valsartan sales, including:

a. List price;
b. Average marginal price;
c. Average wholesale price;
d. Wholesale acquisition cost;
e. Direct price;
f. Average discount off of wholesale price or wholesale acquisition cost;
g. Price under Medicare program;
h. Price under Medicaid program;
i. Maximum allowable price;
j. Average manufacturing price (AMP) as defined by, and reported to, the Centers for Medicare and Medicaid Services;
k. Best price, as defined by, and reported to, the Centers for Medicare and Medicaid Services;
l. Net revenue;
m. Gross sales;
n. Net sales;
o. Units;
p. Gross shipments;
q. All measures of margin, income, earnings, and profits;
r. Unit of volumes sold;
s. Unit of volumes sold net of returns;
t. Total product contribution;
u. All costs and expenses attributable to the product;
v. Sales and distribution cost;
w. Cost of goods sold;
x. Manufacturing costs;
y. Marketing, advertising, promotional, and sales expenses;
z. Depreciable and capital improvements;
aa. Regulatory compliance;
bb. Short-run average variable costs;

cc. Long-run average variable costs;
dd. Fixed costs;
ee. Materials cost;
ff. Labor cost;
gg. Marginal cost;
hh. Rebates, discounts, vouchers, or other product promotions, returns, or charge-backs; and
ii. Coupons or co-pay cards.

108. Documents and communications sufficient to identify every entity that purchased, reimbursed, or compensated you for valsartan from you from January 1, 2010 to the present.

109. Produce all documents relating to contracts for the sale of valsartan from January 1, 2010 to the present including (a) contracts with direct purchasers; (b) contracts that provide that the purchaser will take delivery of valsartan from another entity (such as a wholesaler); and (c) contracts concerning or regarding the payment of chargebacks.

110. Produce complete documentation of the date, manufacturing source, quantity, and recipient of all samples of valsartan provided by defendant.

111. Produce all electronic data in tab-delimited, comma-delimited, or semicolon-delimited ASCII flat text or similar electronic format from January 1, 2010 to the present sufficient to identify all sales of valsartan to purchasers in transaction-by-transaction format, as follows:

a. All direct sales/invoice transactions (as well as any discounts or any other price adjustments or offsets contained in the transaction data) including the following fields: (i) price or dollar amount, (ii) source of the transaction price, (iii) number of units sold, (iv) number of units returned or otherwise affected by the transaction, (v) unit of measure, (vi) date of transaction, (vii) information sufficient to identify the type of transaction (e.g., a sale, a return, a discount, etc.), (viii) NDC, (ix) UPC, (x) SKU, (xi) product description, (xii) product form, (xiii) strength, (xiv) package size in extended units per package, (xv) customer name, (xvi) customer number, (xvii) customer address, (xviii) customer class of trade code and the description of that code (all such customer information being provided for both the bill-to and ship-to customer), and (xix) the customer's parent company (if the data identifies a subsidiary, corporate affiliate, division, satellite office, distribution center, warehouse, or the like).

b. All data concerning chargebacks, rebates, discounts, and other consideration given or accrued relating to valsartan, including the following fields: (i) each transaction, including the date thereof; (ii) the name and address of, and all unique codes or identifiers for, the person, firm corporation, or other business entity whom you paid, or on whose behalf you accrued, the chargeback, rebate, discount and/or other consideration; (iii) the name and address of, and all unique codes or identifiers for, the persons, firms, corporations, or other business entities that made the purchases in respect of which you paid or accrued the chargeback, rebate, discount, or other consideration; (iv) the sales, or groups of sales, upon which the rebate, discount, or other consideration is based, including: (aa) the number of units of the particular product sold, by package size, SKU, UPC, NDC, and any and all other unique codes or other identifiers for each sale or other transaction; (bb) the bill-to customer; (cc) the ship-to customer; (dd) the dates of the sales, or group of sales; (ee) the invoice amount in dollars for the sales or group of sales; (ff) the amount of the chargeback, rebate, discount, or other consideration paid or accrued; and (gg) the contract, agreement, or other basis upon which the chargeback, rebate, discount, or other consideration is calculated.

c. All administrative fee transactions relating to valsartan, including: (i) fee amount paid, (ii) date of payment, (iii) date or date range of sales concerning the fee that was paid, (iv) information sufficient to identify the type of administrative fee (if applicable), (v) customer name, (vi) customer number, (vii) customer address, and (viii) customer class of trade code and the description of that code;

d. For all other transaction types not reflected in (a) through (c) above, produce all documents relating to any other paid or accrued discounts, rebates, chargebacks, billbacks, unit adjustments, price adjustments, shelf-stock price adjustments, returns, third-party returns, error corrections, free goods, nominally-priced goods, whether created or maintained daily, monthly, quarterly, or at some other periodicity, with regard to valsartan.

e. The complete documentation for all items above (a though d) including (i) lookup tables, (ii) data dictionaries, (iii) lists of fields, (iv) descriptions of information contained in those fields (e.g., field lengths, formats, etc.), and (v) descriptions of any codes used in any fields (such as class of trade designations, etc.), including but not limited to (aa) a separate product list, including NDC, SKU, UPC, product description, and package size; (bb) a separate table that lists, for each "bill-to customer" and "ship-to customer," the customer number, parent customer number, customer group number, customer identity, contact information, address, and class of trade (e.g., SIC code); (cc) a separate table listing and defining each transaction code, abbreviation, or other field or entry code, and indicating (1) whether quantity values for each transaction type should be included in calculating net quantity sold, or should be ignored because they do not affect net quantity sold and (2) how negative unit and dollar values should be treated in calculating net quantities and dollar amounts; (dd) all data sets and calculations used to (1) determine accrued rebates and/or chargebacks and/or (2) periodically reconcile accrued rebates and/or chargebacks with actual rebates and/or chargebacks; (vi) return and/or exchange policies; and (vii) payment terms.

XVIII. AVAILABLE DATA SOURCES

112. Produce all documents relating to all IMS, Verispan, MediSpan, Scott-Levin, PriceCheck, ImpactRx, First DataBank, or other pharmaceutical industry data products purchased and or subscribed to or available to you regarding valsartan.

113. Produce all data or reports generated by IMS, CMS, or Verispan, or any comparable third party person or entity (including, but not limited to, Medi-Span, ImpactRx, and First DataBank), in whatever format it was received, relating to the sale, prescription, marketing, promotion, or detailing of valsartan from date of launch to the present for valsartan, including:

a. IMS National Prescription Audit data, including TRx, NRx, extended units, retail sales dollars and retail sales price. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.

b. IMS National Sales Perspective data, including total units, extended units, total sales dollars, and price. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.

c. CMS national Health Expenditures and Drug Utilization data, including TRx, NRx, Medicaid percentage paid, extended units, retail sales dollars, and retail sales price, with regard to valsartan.

d. Verispan Vector One National (VONA) data, including TRx, NRx, extended units, retail sales dollars, and retail sales price, with regard to valsartan. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.

114. Produce all documents relating to any coupon or co-pay assistance you made available to consumers for valsartan.

XIX. DEFENDANT-SPECIFIC REQUESTS

A. To Mylan:

115. Produce all documents, communications, and filings associated with Mylan's ANDA 20473. This includes but is not limited to the initial ANDA submission, subsequent amendments to the ANDA submission, correspondence from the FDA regarding that ANDA submission, responses to correspondence from the FDA regarding that ANDA submission, and any and all supporting documentation filed with the FDA, including bioequivalence information, manufacturing information, and testing regarding ANDA 20473.

116. Produce all inspection documents, including any and all Form 483s, and EIRs, and correspondence from the FDA associated with Mylan's Nashik facility, including but not limited to the September 2016 inspection and resulting warning letter and November 2018 inspection and warning letter.

117. Produce all inspection documents, including any and all Form 483s, and EIRs, and correspondence from the FDA associated with Mylan's Morgantown, WV facility, including but not limited to documents regarding inspections which occurred in November of 2016, March 2018, April 2018, resulting correspondence with the FDA regarding these inspections (including but not limited to, notes, presentations and documents created as a result of in person meetings with regulatory officials).

118. Produce all due diligence documents associated with Mylan's acquisition of Matrix Pharmaceuticals.

119. Produce all documents and communications regarding your contract with Lantech Pharmaceuticals for the recovery and further use of any and all solvents used in valsartan manufacturing.

B. To Aurobindo:

120. All documents and communications regarding your contract with Lantech Pharmaceuticals for the recovery and further use of any and all solvents used in valsartan manufacturing.

C. To Teva:

121. Produce all full and complete documents and document families previously produced in core discovery, including all documents previously withheld by Teva from the custodial file of Constance Truemper.

122. Produce all inspection documents, including any and all Form 483s, and EIRs, and correspondence from the FDA associated with Teva's finished dose manufacturing facilities,

including but not limited to the Jerusalem Oral Solid Dose facility, and documents regarding a 2010 inspection which resulted in a warning letter from the FDA.

Dated: August 30, 2019

/s/ Adam Slater
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CERTIFICATE OF SERVICE

I certify that on the 30th day of August 2019, I electronically transmitted the attached document to counsel of record for all API and Finished Dose Manufacturers via electronic mail.

/s/ Adam M. Slater